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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,573	07/11/2003	Babu J. Mavunkel	219002030100	3779

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EXAMINER

PERLINGER, SARAH E

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,573

Applicant(s)

MAVUNKEL ET AL.

Examiner

Sarah E. Perlinger

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1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02/27/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1 and 5-11 are pending. Claims 2-4 were canceled in the amendment filed on May 12, 2006.

2. ***Claim Rejections - 35 USC § 112***

Applicant's arguments in regard to the 112 first and second paragraph rejections against claims 8-10, filed May 12, 2006 have been fully considered but they are not persuasive. Applicants filed a 37 C.F.R. 1.132 opinion affidavit. The affidavit does not delineate the variation of conditions, starting materials, operating parameters, etc. for amination to proceed. Also, the examples provided in the affidavit are drawn exclusively to heterocyclic nitrogen-containing compounds. Further, all of the examples provided in the affidavit are drawn to electrophilic amination reactions. Finally, the instant disclosure exclusively disclosed operability for the method using the instant claimed compound to aminate an indole compound wherein n of the instant claimed compound was 0. The affidavit has not provided support for the deficiency of the specification in supporting such a broad scope as set forth in the instant claims 8-10. The metes and bounds of the method of claims 8-10 cannot be established due to a lack of written description and the vague terminology used.

3. ***Claim Rejections - 35 USC § 102***

In view of the amendment filed on May 12, 2006 wherein claims 2-4 were canceled, the 102(b) rejection of claims 2-4 has been withdrawn.

4. ***Claim Rejections - 35 USC § 103***

Applicant's arguments filed May 12, 2006 have been fully considered but they are not persuasive.

The 103 rejection against claims 1-7 over Van Assche et al. US 4,472,194 or Tessier et al. US 4,801,717 applies only to claim 7 because claim 7 has a limitation which is different from the invention as a whole. The argument regarding the obviousness rejection directed at a single species of instant claim 7 is irrelevant because the only relevant compound is the trifluoromethyl compound. Applicants have not suggested or admitted that the instant claimed genus of claims 1-6 is patentably distinct from the species of claim 7. Therefore, a reference that anticipates claim 7 would also anticipate claims 1-6.

Furthermore, Applicants argue that the Tessier reference (US 4,801,717) does not clearly guide the reader toward the required trifluoromethyl substituent in formula (I), or toward a phenoxyamine having three substituents as required by claim 1 (see Response, filed May 12, 2006, pages 10-11). Both prior art references however, clearly guided one of ordinary skill in the art to 4-nitro, 2-trifluoromethyl and 4-trifluoromethyl, 2-nitro substituted phenyl hydroxylamine compounds (see US 4,801,717, column 14, Example 33, column 6, line 61 and column 3, line 59 and Van Assche et al. US 4,472,194, column 1, lines 61-62). A survey of the instant specification only revealed examples of 2-nitro-4-(trifluoromethyl) phenylhydroxylamine and 4-nitro-2-(trifluoromethyl)phenylhydroxylamine species of the instant claimed genus (see Specification, pages 3-5, Examples 1-3). One must apply the same standard to the instant invention as has been applied to the prior art. If the prior art lacks guidance and motivation to make the compounds of the instant genus wherein the phenylhydroxylamine is trisubstituted, then the instant application would also lack guidance and motivation to make the compounds of the instant genus wherein the phenylhydroxylamine is trisubstituted. If however, the instant disclosure is supportive of the trisubstituted phenylhydroxylamine genus, then the prior art also supports such genus.

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5. Applicant's arguments, see pages 12-14 of the Response, filed May 12, 2006, with respect to the rejection of claim 11 under 35 U.S.C. 103(a) have been fully considered and are persuasive.

Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection is made under 35 U.S.C. 112 first paragraph.

.....
The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to synthesize the compound of claim I, which method comprises treating a compound of formula (2) with an alkyl hydroxylacylamidate, does not reasonably provide enablement for the instant method wherein a compound of formula (2) is treated with Boc-hydroxylamine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Nature of Invention

The instant claim is drawn to a method to synthesize the compound of claim 1, which method comprises treating a compound of formula (2) with Boc-hydroxylamine.

The State of the Art and Predictability

Unlike the mechanical art, the high degree of unpredictability is well recognized in the chemical synthetic art. A change in the structure of the compound may drastically affect the rate of the chemical reaction.

The Amount of Guidance and Working Examples

The starting materials of claim 11 regarding the Boc-hydroxylamine compound, were not provided in the specification nor was there any reference to making the Boc-hydroxylamine compound

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(see Specification, pages 1-5). Furthermore, the Boc-hydroxylamine compound could not be found in the prior art and therefore one having ordinary skill in the art would not have had access to such compound at the time of the instant invention (see Exhibit A, CAS Search Report). Absent sources, the public is offered mere language, rather than enablement. Ex parte Moersch 104 USPQ 122. In re Howarthe 210 USPQ 689.

Amount of Undue Experimentation

Since insufficient teaching and guidance are provided by the specification, one of ordinary skill in the art, even with a high degree of skill, would not be able to make the Boc-hydroxylamine compound and subsequently would not be able to use the synthesis method of the instant claim 11

The following rejections are necessitated by the amendment to the claims filed on May 12,

2006:

6. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a compound of formula (I) and a method to aminate a nitrogen in a recipient compound by treating such recipient compound with a compound of formula (I) wherein "n=1-3". Upon reviewing the specification, no description of the instant claimed compound of formula (I) wherein n=1-3 could be found. Furthermore, the specification merely provided examples of the compounds of formula (I)

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wherein $n=0$ (see Specification, pages 3-5, Examples 1-3). The amendment of the claims of $n=1-3$ represents NEW MATTER. This is a NEW MATTER rejection. Removal of the new matter is required, see *In re Rasmussen*, 211 USPQ 323.

7. **Conclusion**

None of the claims are allowed.

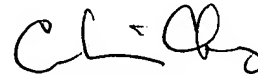
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Sarah E. Perlinger, whose telephone number is (571) 272-5574. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Thomas McKenzie, can be reached at (571) 272-0670. The fax number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



07/13/2006



Celia Chang
Primary Examiner
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